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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED
THERAPIES PRODUCTS LIABILITY
LITIGATION

Case No. 13md2452 AJB (MDD)

**DEFENDANTS' REPLY
MEMORANDUM IN SUPPORT OF
MOTION TO DISQUALIFY DR.
ALEXANDER FLEMING AS AN
EXPERT WITNESS FOR
PLAINTIFFS**

Date: March 12, 2015

Time: 2:00 p.m.

Judge: Hon. Anthony J. Battaglia

Magistrate: Hon. Mitchell D. Dembin

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Case No. 13md2452 AJB (MDD)

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISQUALIFY

1 Plaintiffs concededly disclosed Defendants' confidential documents to Dr.
 2 Alexander Fleming—an individual who founded and currently manages Exsulin, a
 3 company that has developed and currently is testing in humans an anti-diabetes drug
 4 designed to compete with the very medications at issue in this litigation. By failing to
 5 provide Defendants with the advance notice expressly required by the Protective
 6 Order, Plaintiffs denied Defendants the ability to object and to seek to prevent the
 7 disclosure of this material to a competitor.

8 Plaintiffs should not be permitted to capitalize on their violation by continuing
 9 to use Dr. Fleming as an expert in this litigation, and certainly not to opine on matters
 10 related to the very confidential documents that improperly were provided to him by
 11 Plaintiffs' counsel.

12 ARGUMENT

13 A. Plaintiffs disclosed confidential discovery materials to Dr. Fleming in 14 clear violation of the Protective Order.

15 There is no dispute that Plaintiffs knowingly and intentionally disclosed
 16 confidential documents to Dr. Fleming without first providing Defendants notice of
 17 their intention to do so. Opp. at 16. In failing to give Defendants the notice required
 18 by the Protective Order, Plaintiffs deprived Defendants of the opportunity to object
 19 and intervene. *Id.* at 16; ECF No. 564 (Am. Protective Order) ¶ 5(d).¹ Plaintiffs'
 20 single-pronged defense hinges entirely on the faulty premise that Dr. Fleming is not a
 21 “competitor”: the disclosure did not technically violate the Protective Order, they say,
 22 because Exsulin, the company that Dr. Fleming founded and presently leads as Chief
 23 Executive and Chief Medical Officer, is only *testing* the diabetes treatment it has
 24 developed, and has not yet received FDA approval to *market* the product. Opp. at 14.
 25 Plaintiffs' contention is belied the meaning, including the regulatory definition, of the
 26

27
 28 ¹ Novo Nordisk, Inc. joins in the arguments set forth in this brief in addition to its
 separately filed motion to disqualify Dr. Fleming, ECF No. 902.

1 term “manufacturer,” Exsulin’s own representations, and the clear terms of the
2 Protective Order.

3 First, Exsulin is plainly engaged in manufacturing as that term customarily is
4 understood.² FDA regulations expressly define “manufacturing” to include the
5 “*testing*” of prescription medication, including at “*any part of the process.*” 21
6 C.F.R. § 207.3(a)(8) (emphases added). Plaintiffs note that Exsulin is not currently
7 required to *register* with the FDA as a manufacturer, Opp. at 15, but that is only
8 because FDA regulations do not require that all manufacturers register: a company
9 “that *manufactures* its own drug for use in its clinical trial of the drug” is exempt
10 from registration. 71 Fed. Reg. 51276, 51284 (Aug. 29, 2006) (emphasis added).
11 That does not mean, of course, they are not manufacturers. To the contrary, the
12 regulations expressly indicate that companies *making and testing*, but not yet
13 marketing, products *are* manufacturers. Exsulin’s diabetes medication currently is in
14 Phase II clinical trials involving hundreds of patients in the United States and Canada.
15 *See* Exsulin, Investor Overview, *available at* <http://www.exsulin.com/investors2.html>
16 (last accessed Feb. 18, 2015). To state the obvious, Exsulin is manufacturing its
17 medication for use in those human clinical trials.

18 Second, Plaintiffs’ argument is inconsistent with Dr. Fleming’s own
19 representations about his company. Exsulin markets itself to investors, health
20

21 ² Notably, the dictionary broadly defines “manufacturer” as simply “one that
22 manufactures,” *i.e.*, one who makes something “from raw materials by hand or by
23 machinery” or who engages in “the act or process of producing something.”
24 *Merriam-Webster’s Collegiate Dictionary* 709 (10th ed. 1996); *see also American*
25 *Heritage College Dictionary* 843 (4th ed. 2002) (same). Exsulin is plainly engaged in
26 “the act or process of producing” diabetes medication. *See also* Ronald W. Eades,
27 *Jury Instructions on Products Liability* § 3.02.1 at 3-6 (LexisNexis, 4th ed. 2014) (“If
28 you are satisfied from the evidence that the defendant was involved in the design,
assembly, fabrication, production, construction or other preparation of the product, or
a component part of the product that is subject of this litigation prior to the sale of that
product to the user or consumer, then you will find that the defendant is a
manufacturer of that product.”).

professionals, and prospective patients as a **manufacturer** of prescription medication. The company’s website touts that “[f]or the last three years [E]xsulin’s founders operated ‘under-the-radar’ to achieve critical milestones in manufacturing, formulation, animal studies, and clinical trial preparations.” Exsulin, Company Overview, *available at* <http://www.exsulin.com/company.html> (last accessed Feb. 18, 2015). The website also states that Exsulin is dedicated to “the development *and commercialization* of therapies that reverse the fundamental cause of diabetes,” Exsulin, Home Page, *available at* <http://www.exsulin.com/> (last accessed Feb. 18, 2015) (emphasis added), and aims to market its product to 1.2 million patients in North America alone, *see* Exsulin, Investor Overview, *available at* <http://www.exsulin.com/investors2.html> (last accessed Feb. 18, 2015). It defies common sense to suggest that Exsulin is not a competitor vis-à-vis Defendants.

Third, Plaintiffs’ argument is inconsistent with the terms of the Protective Order entered in this case. The Protective Order defines “competitor” as “**any manufacturer or seller** of prescription medications other than the Producing Party, including, without limitation, other Defendants in this Litigation.” ECF No. 564 (Am. Protective Order) ¶ 5(d) (emphasis added). Plaintiffs’ interpretation would render the Protective Order’s definition of “competitor” entirely redundant. *See Bayview Hunters Point Community Advocates v. Metropolitan Transportation Comm’n*, 366 F.3d 692, 700 (9th Cir. 2004) (explaining that courts should avoid a construction “that would render another part” of the contract “superfluous” (internal quotation marks omitted)). If a company were a “manufacturer . . . of prescription medications” only if it were also a “seller of prescription medications,” there would be no need for the Protective Order to define “competitor” as “any manufacturer *or seller* of prescription medications.” ECF No. 564 (Am. Protective Order) ¶ 5(d) (emphasis added).

B. The Court should disqualify Dr. Fleming as an expert witness.

Plaintiffs offer two arguments against disqualification. Neither has merit.

1 First, Plaintiffs argue that Defendants’ motion is not timely. Opp. at 17. This
 2 argument, however, fails from the start, as it arrives unaccompanied by any factual or
 3 legal support. Motions for sanctions under Rule 37 are not subject to any express time
 4 limit, and courts have rejected such motions as untimely only where there has been an
 5 “unreasonable delay” in bringing the motion. *MGA Entertainment, Inc. v. Nat’l*
 6 *Products Ltd.*, 2012 WL 4052023, at *4 (C.D. Cal. Sept. 14, 2012) (collecting cases).
 7 There has been no such delay here.

8 Plaintiffs disclosed Dr. Fleming as an expert witness on preemption on
 9 November 24, 2014. Plaintiffs did not, however, disclose at that time that they
 10 intended to divulge Defendants’ confidential material to Dr. Fleming. Indeed, given
 11 that expert discovery during this phase was to be limited to the issue of preemption,
 12 Defendants had no reason to believe that Plaintiffs would ask Dr. Fleming to offer
 13 wide-ranging opinions on a host of unrelated scientific and medical issues, many of
 14 which extend far beyond his area of expertise. Notably, Defendants did *not* disclose
 15 confidential material to their preemption expert for review in preparing his opening
 16 report, but rather—consistent with their understanding of the Court’s expectations—
 17 asked their expert to focus on FDA policies and practices that shed light on FDA
 18 statements related to the issue of preemption.

19 Defendants only learned that Plaintiffs disclosed confidential material to Dr.
 20 Fleming on December 15, 2014, the day Plaintiffs served his 108-page opening report.
 21 Defendants filed their motion to disqualify approximately one month later, on January
 22 20, 2015. During the intervening month, a period that included the holiday season,
 23 Defendants engaged in meet-and-confer efforts concerning Dr. Fleming’s
 24 disqualification with Plaintiffs’ counsel in the MDL and the JCCP.³ Defendants’
 25 motion to disqualify Dr. Fleming was, if anything, relatively expeditious. And
 26 Plaintiffs do not contend that they showed Dr. Fleming any additional confidential

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 28 ³ Defendants notified the Court of their view that Plaintiffs violated the Protective
 Order in their January 6, 2015, motion to strike and/or seal. See ECF Nos. 882, 883.

1 material between the time they served Dr. Fleming’s report and Defendants filed their
 2 motion to disqualify Dr. Fleming, or that they have otherwise been prejudiced by any
 3 purported delay.

4 Plaintiffs do not cite any authority suggesting that a waiver arises in such
 5 circumstances. Plaintiffs rely on *English Feedlot, Inc. v. Norden Labs, Inc.*, 833 F.
 6 Supp. 1498 (D. Colo. 1993), but that case is inapposite. As an initial matter, *Feedlot*
 7 concerned a motion for disqualification due to a prior confidential relationship; it
 8 therefore did not apply the “unreasonable delay” standard under Rule 37. *Id.* at 1501.
 9 Moreover, the district court in *Feedlot* found the motion untimely because the moving
 10 party waited *over eight months* to file it and plainly filed it as a “mere tactical
 11 maneuver.” *Id.* at 1504. The case in no manner supports Plaintiffs’ ambitious
 12 proposition that the one-month period here constitutes an unreasonable delay. *See*
 13 *also Gardner v. Toyota Motor Corp.*, 2010 WL 3733876, at *4 n.1 (W.D. Wash. Sept.
 14 1, 2010) (“The court finds that Toyota did not unreasonably delay its request for Rule
 15 37 fees, given that the order granting the motion to compel was entered less than two
 16 months before the motion for sanctions was filed.”).

17 Second, Plaintiffs contend that their breach of the Protective Order was
 18 harmless because the documents they disclosed to Dr. Fleming “include[d] no actual
 19 trade secrets, like pricing data or manufacturing techniques.” Opp. at 19. But there
 20 can be no dispute that the confidential documents Plaintiffs’ counsel provided to Dr.
 21 Fleming contain sensitive discussions and reports concerning, *inter alia*, Defendants’
 22 study designs and preliminary study results relating to the drugs at issue in this
 23 litigation,⁴ as well as twenty-one deposition transcripts of defense witnesses, *see*
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25 ⁴ *See, e.g.*, MRKJAN0000205038; MRKJAN0000552189; MRKJAN0000930499;
 26 MRKJAN10000281236. Indeed, Plaintiffs disclosed to Dr. Fleming numerous
 27 documents designated *Attorneys’ Eyes Only*—*i.e.*, documents so confidential that
 28 defense counsel cannot even disclose them to their own clients. *See, e.g.*, Fleming
 Expert Report, Appx. B (noting that Dr. Fleming reviewed MRKJAN0000892492,
 MRKJAN0000930329, NOVO-01052171, AMYLN05278007, AMYLN05310370,
 -5- Case No. 13md2452 AJB (MDD))

1 Fleming Report, Appx. B, at 12, all of which contain confidentiality designations.
 2 One of the central purposes of a Protective Order in cases such as this is to prevent the
 3 disclosure of this very type of information to Defendants’ competitors, such as Dr.
 4 Fleming, whose company is currently addressing “[c]omplicated safety and efficacy
 5 issues” that are “closely related to those of the incretin drug products” with respect to
 6 a drug that is intended to compete with Defendants’ drugs. Fleming Report at 3.
 7 Unfortunately, Dr. Fleming cannot unlearn this information— “[i]t is very difficult for
 8 the human mind to compartmentalize and selectively suppress information once
 9 learned, no matter how well-intentioned the effort may be to do so.” *BASF Corp. v.*
 10 *United States*, 321 F. Supp. 2d 1373, 1380 (C.I.T. 2004) (internal quotation marks
 11 omitted).

12 Plaintiffs’ violation of the Protective Order is prejudicial because it prevented
 13 Defendants from asserting a valid objection to the disclosure of their confidential
 14 material to their competitor. *See* Mot. at 4-5. Put simply, the rights of notification
 15 exist in the Protective Order to give Defendants the opportunity to object and have this
 16 Court consider their objections *before* information is disclosed to a competitor. It is
 17 not up to Plaintiffs to decide that Defendants would not have exercised this right or
 18 this Court would not have granted their motion.

19 Defendants explained in their opening memorandum that a “crucial factor” in
 20 determining whether a party may disclose confidential material to an expert who
 21 works for a competitor is whether the expert is a “competitive decision-maker” at that
 22 company. *Santella v. Grizzly Indus., Inc.*, 2012 WL 5399970, at *4-5 (D. Or. Nov. 5,
 23 2012). Plaintiffs are silent on this point, perhaps in recognition of Dr. Fleming’s
 24 capacity as Co-Founder, Chairman, and Chief Medical Officer of Exsulin. Dr.

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 26 and AMYLN05318927, which are designated “Attorneys’ Eyes Only”). So as not to
 27 burden the Court with another motion to seal, Defendants are not attaching these
 28 documents as exhibits to this motion, but will provide copies to the Court upon
 request.

1 Fleming plainly is “in a position to effectuate or direct decisions made using
 2 knowledge that is tainted by [Defendants’] confidential information.” *Id.* at *6
 3 (internal quotation marks omitted); *see also Wang Laboratories, Inc. v. CFR*
 4 *Associates, Inc.*, 125 F.R.D. 10, 13 (D. Mass. 1989) (good cause shown for preventing
 5 disclosure of a party’s confidential documents to expert who admitted in his resume
 6 that he currently consults with companies about competing products).

7 Likewise, Plaintiffs ignore authority that disqualification is an appropriate
 8 sanction in such circumstances and fail to cite authority to the contrary. *See* Mot. at 5
 9 (citing *Frazier v. Layne Christensen Co.*, 2005 WL 372253 (W.D. Wis. Feb. 11, 2005)
 10 (Crocker, Mag. J.); *Irwin Seating Co. v. IBM*, 2007 WL 518866, at *3 (W.D. Mich.
 11 Feb. 15, 2007)). Plaintiffs’ disclosure of Defendants’ confidential material to their
 12 competitor is a serious violation of an order entered by this Court, and it warrants Dr.
 13 Fleming’s disqualification.

14 **C. At a minimum, the Court should strike portions of Dr. Fleming’s**
 15 **report that refer to or rely upon confidential discovery materials.**

16 In their opening memorandum, Defendants argued that if the Court does not
 17 strike Dr. Fleming as an expert witness, the Court should strike the portions of Dr.
 18 Fleming’s report that rely on or reference confidential material disclosed to Dr.
 19 Fleming in violation of the Protective Order. Mot. at 5-6. Plaintiffs do not dispute
 20 that striking these portions of the report would be an appropriate remedy for Plaintiffs’
 21 violation. Accordingly, at a minimum, the Court should strike these portions of the
 22 report as a sanction for Plaintiffs’ clear violation of the Protective Order.

23 **CONCLUSION**

24 For the reasons stated above, Defendants respectfully request that the Court
 25 disqualify Dr. Fleming from serving as an expert witness for Plaintiffs in this
 26 litigation and strike his preemption expert report in its entirety, or in the alternative,
 27 provide the equitable relief this Court deems appropriate, including but not limited to
 28

1 striking the sections of his report that rely upon confidential material submitted to Dr.
2 Fleming in violation of the Protective Order.

3
4 Dated: February 18, 2015

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14
15 **SIGNATURE ATTESTATION**

16 I hereby certify that authorization for the filing of this document has been
17 obtained from each of the other signatories shown above and that all signatories
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